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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,649	10/18/2001	Markus Baur	88265-10173	8748

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WINSTON & STRAWN
PATENT DEPARTMENT
1400 L STREET, N.W.
WASHINGTON, DC 20005-3502

EXAMINER

LANKFORD JR, LEON B

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 09/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/982,649

Applicant(s)

BAUR ET AL.

Examiner

L Blaine Lankford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 14-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/091483.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

The examiner concurs with applicant's representative that claims 12 & 13 should be examined with claims 1-11.

Claims 14-19 are withdrawn without traverse.

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention nor to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Generic claims 1-7 & 9-11 imply that diverse cell lines other than the deposited strains with the claim designated properties can be made using the method disclosed in the specification without undue experimentation.

Whether or not the disclosure provides an enabling disclosure, it does not provide a written description of the desired cell lines which is necessary to provide a written description of the generic cell lines. The functional property is not itself a written description of those cell lines, it conveys no distinguishing information concerning its identity, just its functional property. While the disclosure provides a process for obtaining additional cell lines with the claimed properties, there is no further information in the application pertaining to the desired cell lines characteristics; in other words, it does not describe cell lines having the desired functional property in general. Describing a method of making a suitable cell lines having the desired functional property, as in the example, does not necessarily describe the desired cell lines itself.

Every species in a genus need not be described in order that a genus meet the written description requirement. See *Utter*, 845 F.2d at 998- 99, 6 USPQ2d at 1714 ("A specification may, within the meaning of § 112, first paragraph, contain a written description of a broadly claimed invention without describing all species that claim encompasses.") In claims to an species from a genus, however, a generic statement without more, is not an adequate written description of the genus because it does not distinguish the claimed species of the genus from others, except by the alleged function. It does not specifically define any of the species of that genus that fall within its definition. It does not define any features (as commonly used in the art of cell biology) which are commonly possessed by members of the genus that distinguish them from

others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, does not suffice to define the genus because it is only an indication of what the genus does, rather than what it is. See *Fiers*, 984 F.2d at 1169-71, 25 USPQ2d at 1605- 06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such species of the genus may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.")). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Regarding claim 8: It is apparent that the cell lines are required to practice the claimed invention. As a required element it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the cell line is not so obtainable or available, the requirements of 35 USC 112 may be satisfied by a deposit of the cell line. See 37 C.F.R. 1.802. The art of cell isolation is unpredictable. Therefore to isolate the identical cell line possessing the identical morphological and

biochemical properties as the claimed cell lines would require undue experimentation by one of ordinary skill in the art.

As a deposit has been made under the terms of the Budapest Treaty, an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific cell line will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

In addition the identifying information set forth in 37 C.F.R. 1.809(d) should be added to the specification. See 37 C.F.R. 1803-1.809 for additional explanation of these requirements.

Claim Rejections - 35 USC §102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

OR

Claim Rejections - 35 USC §103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-13 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Boukamp et al(AJ) or Steinkraus et al(AO)

Applicant claims an immortalized cell line.

Boukamp and Steinkraus teach immortalized keratinocyte cell lines. The references are silent on many of the claimed characteristics however as the cell lines share other disclosed properties, it would appear that the reference cell lines would inherently have those properties.

Consequently, the claimed cell lines appear to be anticipated by the aforementioned references.

However, even if the reference's cell line and the claimed cell lines are not one and the same and there is, in fact, no anticipation, the reference cell lines would, nevertheless, have rendered the claimed cell lines obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the clear close relationship between the cell lines as evidenced by their being the same cell type and their close structural and functional relationship.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not Applicants' cell lines differ and, if so, to what extent, from that discussed in the references. Therefore, with the showing of the references,

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the burden of establishing non-obviousness by objective evidence is shifted to

Applicants.

Note that MPEP § 706.3(e) states that:

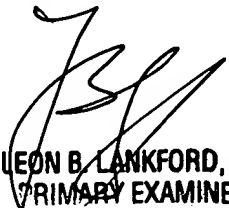
"[w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 35 U.S.C. 102 or 35 U.S.C. 103 of the statute is appropriate. As a practical matter, the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith. A lesser burden of proof is required to make out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional fashion. *In re Brown*, 59 CCPA 1063, 173 USPQ 685 (1972) ; *In re Fessmann*, 180 USPQ 324 (CCPA1974)."

Furthermore, Keratinocytes and melanocytes were well known at the time the invention was made as was the SV40 immortalization method. Given that and the motivation/desire to make immortalized cell lines from these cell types which is provided by the two cited reference, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the references, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to L Blaine Lankford whose telephone number is 308-2455. The examiner can normally be reached on Mon-Thu 7:30-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-0196.


LEON B. LANKFORD, JR.
PRIMARY EXAMINER